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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,580	04/25/2005	Jin-Hoi Kim	P27726	4797
7055	7590	01/30/2007	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C.			MAKAR, KIMBERLY A	
1950 ROLAND CLARKE PLACE			ART UNIT	PAPER NUMBER
RESTON, VA 20191			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE		
31 DAYS	01/30/2007	ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 01/30/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/532,580	KIM, JIN-HOI	
	<b>Examiner</b> Kimberly A. Makar	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 12 September 2005.  
2a)  This action is **FINAL**.                            2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 13-61 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 13-61 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ . 5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 13-25, drawn to porcine uroplakin II promoters and expression vector.

Group II, claim(s) 26-34, drawn to fertilized ovas comprising vectors comprising porcine uroplakin II promoters.

Group III, claim(s) 35-52, drawn to transgenic animals comprising vectors further comprising porcine uroplakin II promoters.

Group IV, claim(s) 53-61, drawn to methods of producing useful proteins utilizing porcine uroplakin II promoters.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions lack unity. Kwon et al (Cloning, Sequencing and Expression Analysis of the Porcine uroplakin II gene, Biochemical and Biophysical Research Communications, 2002. 293:862-869) listed in applicant's 1449 IDS form dated 09/12/05, discloses a porcine uroplakin II promoter in May 2002. The 5' flanking region comprising the promoter is disclosed in figure 3.

3. The technical feature of group I, drawn to porcine uroplakin II promoters and expression vectors is distinct from the technical feature of group II, drawn to fertilized ovas comprising vectors comprising porcine uroplakin II promoters. The promoter and vector sequences of group I can be used in alternate experiments, such as a probe for an immunoblot, or as a vehicle for protein expression in a different cell type. Additionally the ova of group II can be transduced with alternate vectors and promoters than those disclosed in group I. As such, groups I and II are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

4. The technical feature of group I, drawn to porcine uroplakin II promoters and expression vectors, is distinct from the technical feature of group III, drawn to transgenic animals comprising vectors further comprising porcine uroplakin II promoters. The

promoter and vector sequences of group I can be used in alternate experiments, such as a probe for an immunoblot, or as a vehicle for protein expression in cell culture, and not for the production of transgenic animals. Additionally the transgenic animals of group III can be produced with alternate vectors and promoters than those disclosed in group I. As such, groups I and III are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

5. The technical feature of group I, drawn to porcine uroplakin II promoters and expression vectors is distinct from the technical feature of group IV, drawn to methods of producing useful proteins utilizing porcine uroplakin II promoters. The promoter and vector sequences of group I can be used in alternate experiments, as a probe for an immunoblot, or as substrate for a PCR amplification reaction, and not for the production of proteins. Additionally the methods of group IV can be performed with alternate vectors and promoters than those disclosed in group I. As such, groups I and IV are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

6. The technical feature of group II, drawn to fertilized ovas comprising vectors comprising porcine uroplakin II promoters is distinct from the technical feature of group III, drawn to transgenic animals comprising vectors further comprising porcine uroplakin II promoters. The ova of group II can be used in alternate experiments, such as a vehicle for protein expression in cell culture, and not for the production of transgenic animals. Additionally the transgenic animals of group III can be produced with alternate materials, such as from injected blastocysts and not the ova disclosed in group II. As such, groups II and III are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

7. The technical feature of group II, drawn to fertilized ovas comprising vectors comprising porcine uroplakin II promoters is distinct from the technical feature of group IV, drawn to methods of producing useful proteins utilizing porcine uroplakin II promoters. The ova of group II can be used in alternate experiments, such as a vehicle for RNA material for array assays, and not for methods of producing useful proteins utilizing porcine uroplakin II promoters. Additionally, the methods of group IV can be performed with alternate cell types and not the ova disclosed in group II. As such, groups II and IV are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

8. The technical feature of group III, drawn to transgenic animals comprising vectors further comprising porcine uroplakin II promoters is distinct from the technical feature of group IV, drawn to methods of producing useful proteins utilizing porcine uroplakin II promoters. The transgenic animals of group III can be used for alternate experiments other than the production useful proteins, such as an assay to determine compounds capable of stimulating the expression of the porcine uroplakin II promoter in vivo. Additionally, the methods of group IV can be performed in vitro without the transgenic animals disclosed in group III. As such, groups III and IV are biologically, compositionally and functionally distinct, and are thus capable of supporting individual patents.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/01/07/07

  
DAVID GUZO  
PRIMARY EXAMINER